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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,133	02/05/2002	Howard Kaufman	MDS-013AC2	8486

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EXAMINER

MOSS, KERI A

ART UNIT PAPER NUMBER

1743

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/068,133

Applicant(s)

KAUFMAN ET AL.

Examiner

Keri A. Moss

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/12/06
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33,34,38,42,43,46,48,49,54-56 and 59-71 is/are pending in the application.
- 4a) Of the above claim(s) 71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33,34,38,42,43,46,48,49,54-56 and 59-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 33,34,38,42,43,46,48,49,54-56 and 59-71 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/12/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Amendment filed June 12, 2006 has been acknowledged. Claims 33-34, 38, 42-43, 46, 48-49, 54-56 and 59-71 are pending.

Response to Amendment

2. Election/Restriction requirement has been maintained.

New Restriction requirement of claim 71 has been made.

Objection to drawings is withdrawn in light of applicant's amendment to the claims.

Rejections of claims 33-60 as indefinite are withdrawn in light of applicant's amendments.

Rejections of claims 33-34, 38, 40-45, 48-49, 51-56, 58 and 60 under Tadrous is withdrawn in light of applicant's arguments and amendments.

New grounds of rejection of all pending claims under Hochman (USP 5,845,639) in view of Richards-Kortum has been made in light of applicant's amendments.

Election/Restrictions

3. Applicant's election with traverse of claim 38 from claims 36,37 and 39 in the reply filed on June 12, 2006 is acknowledged. The traversal is on the ground(s) that applicant has amended the independent claim. This is not found persuasive because the amended language has not changed that it would require a burdensome search to find each of the methods disclosed in claims 36, 37 and 39.

The requirement is still deemed proper and is therefore made FINAL.

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 33-34, 38, 42-43, 46, 48-49, 54-56 and 59-70, drawn to a method of compensating for sample motion, classified in class 382, subclass 294.
 - II. Claim 71, drawn to a system for performing spectral analysis, classified in class 382, subclass 133.

The inventions are distinct, each from the other because of the following reasons:

5. Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process as claimed can be practiced by another and materially different apparatus such as one without a detector as the unaided eye can obtain spectral data from a sample as a function of location.

6. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

7. During a telephone conversation with Dr. William Haulbrook on August 3, 2006 a provisional election was made to prosecute the invention of Group 1, claims 33-34, 38, 42-43, 46, 48-49, 54-56 and 59-70. Affirmation of this election must be made by

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is
applicant in replying to this Office action. Claim 71[^] withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 38 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear whether applicant refers to a device that obtains spectral data or one that obtains a plurality of sequential images or an additional device.

Claim 38 recites the limitation "a detection device" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

11. Claims 33, 38, 42-43, 48, 54-56 and 60-67, and 70 are rejected under 35 U.S.C. 102(a) as being anticipated by Hochman (USP 5845639). Hochman teaches a method for compensating for sample motion in the spectral analysis of a sample (columns 17-18), comprising applying a chemical agent to a sample (column 39),

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obtaining spectral data from the sample as a function of location (can be done by the user's eye column 40 lines 4-47), obtaining a plurality of sequential images of the sample (column 39), and aligning a subset of said plurality of images to compensate for sample motion (column 39) between the sample and the camera (column 17 lines 17-55). The spectral data comprises both reflectance (column 39) and fluorescence data (column 15 lines 5-11) and is obtained at substantially the same time the images are obtained as the eye can view the images as soon as they are obtained. The chemical agent interacts with the sample to alter an optical signal produced by the sample (column 5 lines 14-39) at least in part by an endogenous chromophore such as hemoglobin (column 15 lines 5-11). This method further comprises determining a characteristic of an area of the sample, such as detecting an artifact that comprises an extraneous portion of an optical field of view (paragraph bridging columns 17 and 18). The location is corrected according to aligned images (columns 17-18). The sample is in vivo tissue (column 4 lines 51-67). The method also includes determining an area of the sample to biopsy (column 3 lines 3-10). The determining step comprises accounting for glare (paragraph bridging columns 18-19). This method can be used to determine abnormal health of tissues (column 40 lines 37-47).

Hochman also discloses an article of manufacture having computer-readable program means with computer-readable instructions embodied thereon for performing the method for compensating for sample motion (columns 18-21).

Claim Rejections - 35 USC § 103

12. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

13. Claims 34, 46, 49, 59 and 68-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hochman in view of Richards-Kortum (USP 6,241,662). Hochman does not disclose using a chemical agent selected from a group consisting of acetic acid, formic acid, propionic acid and butyric acid nor applying the agent to the skin nor sample comprising human cervical tissue. Richards-Kortum teaches using acetic acid specifically for epithelial tissue such as cervical (column 2 lines 43-65). Acetic acid is used to distinguish normal tissue from abnormal tissue (column 4 lines 47-67), specifically precancerous tissue such as CIN II or III (column 2 lines 56-65). An advantage of acetic acid is that it enhances the optical return signal of illuminated tissue during fluorescence microscopy (column 2 lines 43-65). Therefore it would have been obvious to one of ordinary skill in the art to combine the imaging method of Hochman with Richards-Kortum's use of acetic acid as a chemical agent for enhancing the optical signal in fluorescence detection and with Richards-Kortum's use of cervical cells in order to gain the additional advantage of detecting abnormal cervical cells.

Response to Arguments

14. Applicant's arguments, see Amendment, filed June 12, 2006, with respect to the rejection(s) of claim(s) 33-34,38,40-45,48-49,51-56, 58 and 60 under Tadrous have

been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Hochman and Richards-Kortum.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keri A. Moss whose telephone number is 571-272-8267. The examiner can normally be reached on 9-5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KAM 8/4/06


Jill Warden
Supervisory Patent Examiner
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